## REMARKS

Claims 1, 8, 17, and 21 are pending. Claims 2-7, 9-16, 18-20, 22, and 23 are cancelled without prejudice to Applicants' right to pursue the subject matter of those claims in a future continuation or divisional application. Claims 8 and 21 are previously presented. Claims 1 and 17 are currently amended. Support for the amendments can be found *inter alia* in paragraphs 75, 86 and 87 of the specification. These amendments do not introduce new matter.

### Rejections Under 35 U.S.C. §103(a)

Claims 1, 8, 17, and 21 are rejected under 35 U.S.C. §103(a) as unpatentable over Hollander (U.S. Pub. 2006/0105939) in view of an on-line NIH news alert ("The Use of Secretin to Treat Autism" Internet document dated 08/17/2001), and further in view of Swain (E. Swain, Pharmaeceutical and Medical Packaging News (1999)) and PIERCE (PIERCE Technical Resource Sheet TR0043.0 "Protein Stability and Storage" 6/03). The Examiner takes the position that Hollander teaches treating autism with oxytocin, and discloses agents suitable for use in combination therapy. The Examiner also asserts that NIH News Alert teaches treating autism with secretin. The Examiner further asserts that (1) Swain teaches that packaging of pharmaceuticals can be beneficial; and (2) PERCE teaches that protease inhibitors are added to protein solutions to lengthen shelf life.

In reply, applicants respectfully traverse the rejection. Applicants submit herewith a Declaration pursuant to 37 C.F.R. § 1.131 of Dr. Martha Welch, an inventor of the claimed invention, declaring that the invention was conceived of prior to at least August 17, 2001. The Hollander reference was filed as a U.S. national phase application of a PCT application filed on October 3, 2003. The present application claims priority to a U.S. provisional application which was filed on November 6, 2003. The Hollander reference can therefore be removed as prior art based on the Welch Declaration. Without the Hollander reference, the remaining three references cited by the Examiner do not teach or suggest the claimed invention.

In addition, applicants assert that there would have been no motivation to combine the references cited in view of teachings in those references to the contrary. Moreover, the

combination of the references would not have made obvious to a person of ordinary skill in the art a composition as claimed that is a synergistic composition.

In the paper filed on February 28, 2007 in response to the Office Action dated August 31, 2006, Applicants pointed out that the references in combination failed to show the synergistic effect of oxytocin and secretin. The Examiner did not accept the argument because the feature was "not recited in the rejected claim(s)." The Examiner explained that "[a]lthough the claims are interpreted in light of the specification, limitations from the specification are not read into the claims."

In view of that, Applicants have amended claim 1 to recite "a therapeutically effective amount of secretin in synergistic combination with a therapeutically effective amount of oxytocin." Applicants have also amended claim 17 accordingly. Claims 8 and 21 are dependent claims that do not need to be amended. Support for the amendments can be readily found throughout the specification. For example, paragraphs [0075], [0086], and [0087] of the specification specifically refer to the synergistic therapeutic effect of the claimed combination of oxytocin and secretin. In addition, results shown in Figure 22 (as described in paragraph [0047]) demonstrate that treatment with the combination of oxytocin and secretin leads to a resolution of inflammatory infiltrates. Paragraph [0230] further explains that in IL10-/- mouse, after I.P. infusion of secretin alone, there was a partial resolution of inflammation. In comparison, there was an almost complete resolution of inflammation with combined secretin/oxytocin treatment.

The NIH alert states "Although secretin is generally considered safe for single dose diagnostic use, no data are available yet as to the safety of repeated doses over time and no data have been submitted on its safety and efficacy for children." This discloses a single dose use, but there is no information on repeated doses, and no information on the use in children. The alert does not provide any reasonable expectation of success that secretin will work with repeated doses, in children, and let alone that a combination of secretin and oxytocin will have a synergistic effect to treat autism.

**Conclusion**

In view of the foregoing amendments and remarks, Applicants believe that all the rejections have been overcome and that the application is therefore in condition for allowance. The Examiner is invited to call the undersigned at the number listed below in order to expedite the prosecution of this application.

Respectfully submitted,

Dated: October 26, 2007

/Jane M. Love, Ph.D./
Jane M. Love, Ph.D.
Registration No.: 42,812

Wilmer Cutler Pickering Hale and Dorr LLP
399 Park Avenue
New York, NY 10022
Tel: (212) 937-7233
Fax: (212) 230-8888